

National Notifiable Diseases Surveillance System (NNDSS)

OMB Control Number 0920-0728

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Program Contact

Umed A. Ajani
Associate Director for Science
Division of Health Informatics and Surveillance
Center for Surveillance, Epidemiology and Laboratory Services
Centers for Disease Control and Prevention
1600 Clifton Rd, MS-E91
Atlanta, GA 30329
Phone: (404) 498-0258
E-mail: uajani@cdc.gov

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Circumstances of Change Request for OMB 0920-0728

This is a non-substantive change request for OMB No. 0920-0728, expiration date 04/30/2023, for the reporting of Nationally Notifiable Diseases. Information on proposed disease-specific data elements to be added through this non-substantive change request is enumerated in the table below:

Disease Name in NNDSS Collection	Nationally Notifiable (NNC) OR Under Standardized Surveillance (CSS)	Current Case Notification (Y/N)	Proposed Case Notification (Y/N)	Current Disease-specific Data Elements (Y/N)	Proposed Disease-specific Data Elements (Y/N)	Number of Existing Data Elements in NNDSS	Proposed Number of new NNDSS Data Elements
Anthrax	NNC			Y		79	29
Brucellosis	NNC			Y		201	15
Carbon Monoxide Poisoning	NNC			Y		49	1
Hansen’s Disease	NNC			Y		47	25
Leptospirosis	NNC			Y		71	23
<i>Neisseria meningitidis</i>	NNC			Y		92	1
2019 Novel Coronavirus Disease (COVID-19)	NNC			Y		49	14

The National Notifiable Diseases Surveillance System (NNDSS) is the nation’s public health surveillance system that enables all levels of public health (local, state, territorial, federal and international) to monitor the occurrence and spread of the diseases and conditions that CDC and the Council of State and Territorial Epidemiologists (CSTE) officially designate as “nationally notifiable” or as under “standardized surveillance.” The NNDSS program creates the infrastructure for the surveillance system and facilitates the submission and aggregation of case notification data voluntarily submitted to CDC from 60 jurisdictions: public health departments in every U.S. state, New York City, Washington DC, 5 U.S. territories (American Samoa, the Commonwealth of Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands), and 3 freely associated states (Federated States of Micronesia,

the Republic of the Marshall Islands, and the Republic of Palau). The NNDSS also facilitates relevant data management, analysis, interpretation and dissemination of the information. The data are used to monitor the occurrence of notifiable conditions and to plan and conduct prevention and control programs at the state, territorial, local and national levels.

This request is for the addition of 108 new disease-specific data elements: 29 new disease-specific data elements for Anthrax Disease, 15 new disease-specific data elements for Brucellosis, 1 new disease-specific data element for Carbon Monoxide Poisoning, 25 new disease-specific data elements for Hansen’s Disease, 23 new disease-specific data elements for Leptospirosis, 1 new disease-specific data element for *Neisseria meningitidis*, and 14 new disease-specific data elements for 2019 Novel Coronavirus Disease (COVID-19).

Anthrax	
The impetus/urgency for CDC to add data elements for this condition	<ul style="list-style-type: none"> • To allow Bacterial Special Pathogens Branch (BSPB) to conduct enhanced domestic surveillance for anthrax due to the potential for <i>Bacillus anthracis</i> to be used as a bioweapon, the potential for severe illness, and the potential need to distribute antitoxin from the Strategic National Stockpile. • To aid in identifying other individuals who may be at risk of infection, information about occupation and location of potential exposures is needed. • To aid in interpreting laboratory results to classify a case, vaccination, antimicrobial prophylaxis, and treatment data elements are needed. • To evaluate if appropriate medications were dispensed and whether more communication needs to occur among clinicians; additionally, antimicrobial prophylaxis and treatment duration related data elements may potentially aid in determining if the pathogen is resistant to any antimicrobials. • To help with determining specific risk factors for severe illness and allow linkages between epidemiologic and laboratory data for

		case classification.	
Data Element Name	Data Element Description	Value Set Code	CDC Priority ¹
Medical Record ID	TBD	N/A	TBD
State Postal Code	TBD	N/A	TBD
Occupation State	TBD	TBD	TBD
Occupation County	TBD	TBD	TBD
Is the Subject a First Responder	Is the Subject a First Responder	PHVS_YesNoUnknown_CDC	TBD
What category of vaccine did the subject get	What category of vaccine did the subject get	TBD	TBD
Date last received	Date last received anthrax vaccine	N/A	TBD
Booster Vaccine	If received a full series of pre-exposure vaccine, is the subject up-to-date on the annual booster vaccine	PHVS_YesNoUnknown_CDC	TBD
Medication Received	If the case patient received post exposure antimicrobials, indicate the antimicrobials received	TBD	TBD
Start Date of Treatment or Therapy	What was the date that the case patient started taking antimicrobials	N/A	TBD
Date Treatment or Therapy Stopped	What was the date that the case patient stopped taking antimicrobials	N/A	TBD
Signs and Symptoms	Signs and symptoms associated with Anthrax	TBD	TBD
Signs and Symptoms Indicator	Indicator for associated signs and symptoms	PHVS_YesNoUnknown_CDC	TBD
Diet	TBD	TBD	TBD
Smoking Status	What is the patient's current tobacco smoking status?	TBD	TBD
Laboratory State	State where laboratory is located	PHVS_State_FIPS_5-2	TBD
Laboratory City	TBD	N/A	TBD
CSID	CDC specimen ID number from the 50.34 submission form. Example format (10-digit number): 3000123456.	N/A	TBD

¹ R=Required; 1=Priority 1, 2=Priority 2, 3=Priority 3

Specimen Collected before antibiotics	Was the specimen used for testing collected before antibiotics was taken?	PHVS_YesNoUnknown_CDC	TBD
Transferred from Initial Hospital	Transferred from Initial Hospital	PHVS_YesNoUnknown_CDC	TBD
Antimicrobials given for illness	Antimicrobials given for illness	PHVS_YesNoUnknown_CDC	TBD
Antimicrobial Name	Antimicrobial Name	TBD	TBD
Antimicrobial Start Date	Antimicrobial Start Date	N/A	TBD
Antimicrobial End Date	Antimicrobial End Date	N/A	TBD
Number of Days of Treatment	Number of Days of Treatment	N/A	TBD
Actual Route of Administration - Attempted or Completed	What is the route of antibiotic administration?	TBD	TBD
Date AIG Given	Date AIG Given	N/A	TBD
Date Raxibacumab Given	Date Raxibacumab Given	N/A	TBD
On vasopressors for any length of time	On vasopressors for any length of time	PHVS_YesNoUnknown_CDC	TBD

Brucellosis		Value Set Code	CDC
The impetus/urgency for CDC to add data elements for this condition	<ul style="list-style-type: none"> To allow Bacterial Special Pathogens Branch (BSPB) to conduct enhanced domestic surveillance for brucellosis. Monitoring <i>Brucella</i> spp.-related exposures and infections is important, due to the pathogen's select agent status and the potential for the pathogen to cause severe illness. To allow for appropriate follow-up and monitoring of exposures to <i>Brucella</i> spp. in laboratory and occupational settings which can lead to infection. To help BSPB learn more about risk factors for brucellosis, track cases' treatment to reduce the risk of relapse, identify situations where others may have been exposed (and potentially identify case clusters), and track exposure events to mitigate the risk of developing brucellosis. To help BSPB update recommendations for case and exposure monitoring, inform outreach activities, and target health communications to populations that are at higher risk of being exposed to <i>Brucella</i>. 		
Data Element	Data Element Description	Value Set Code	CDC

Name			Priority (New)
Clinical Presentation	Clinical presentation associated with the illness being reported	TBD	TBD
Clinical Presentation Indicator	Indicator for associated clinical presentation	PHVS_YesNoUnknown_CDC	TBD
Date of Clinical Presentation	The date and time, if available, of onset of clinical presentation	N/A	TBD
Medication administered	Name of antibiotic administered to subject/patient for this illness	TBD	TBD
Medication Administered Dose	Dose of the antibiotic received	N/A	TBD
Date Treatment or Therapy Started	Date the treatment or therapy was started	N/A	TBD
Treatment Duration	Prescribed duration (in days) of antibiotic treatment	N/A	TBD
Type of animal	What type of animal did the patient have contact with, or acquire food products from?	TBD	TBD
Animal Ownership	Who owns the animals?	TBD	TBD
Type of contact	What type of activity was the case/patient engaged in that led to contact with the animal(s)?	TBD	TBD
Country of Product Acquisition	Where was the food product acquired?	TBD	TBD
Disease Presentation	The duration in which the disease presented	TBD	TBD
Food Product consumed	What type of animal-based food product did the patient consume?	TBD	TBD
Contact Type	If linked to confirmed case or contact with similar illness or signs and	TBD	TBD

	symptoms, indicate type of contact.		
Similar Illness Contact	Did the case/patient know anyone else with a similar illness?	TBD	TBD

<i>Carbon Monoxide Poisoning</i>			
The impetus/urgency for CDC to add data elements for this condition	<ul style="list-style-type: none"> To make surveillance more comprehensive and informative for public health actions including public health policy. To enhance surveillance to learn about the effects of long-term exposures to low levels of CO and monitor trends in high risk groups. Additional data would help to better target outreach activities to those at increased risk for CO poisoning. 		
Data Element Name	Data Element Description	Value Set Code	CDC Priority (New)
Work Site of Exposure	If a work setting where the exposure occurred, please indicate specific site.	TBD	2

<i>Hansen's Disease</i>			
The impetus/urgency for CDC to add data elements for this condition	<ul style="list-style-type: none"> To improve CDC's understanding of Hansen's disease epidemiology, identify challenges to diagnoses, and also possibly prevent further transmission and lifelong disability given the increase in disease incidence and lack of information related to type of leprosy, family or household contacts, treatment received, or even history or previous diagnosis that is currently received via current notifications to CDC 		
Data Element Name	Data Element Description	Value Set Code	CDC Priority (New)
History of Previous Illness	Was the patient previously diagnosed with Hansen's disease?	Yes No Unknown (YNU)	TBD
Date of Previous Illness	Date of previous Hansen's Disease diagnosis	N/A	TBD
Number of doctors seen	How many doctors has the patient seen for this problem?	Yes No Unknown (YNU)	TBD
Biopsy Performed	Was a biopsy performed on	Yes No Unknown (YNU)	TBD

	the patient as a result of Hansen's disease?		
Biopsy Results	TBD	TBD	TBD
Biopsy Interpretation	Indicate the results of the biopsy	TBD	TBD
Date of Previous Biopsy	If biopsy was performed on the patient, indicate the date of biopsy.	N/A	TBD
Previous Residence	List all places in the US. and all foreign countries a PATIENT resided (including military service) BEFORE leprosy was diagnosed.	TBD	TBD
Relation to Known or Suspected Contact	TBD	TBD	TBD
Household contacts Examined	Have any household contacts of the patient been examined	Yes No Unknown (YNU)	TBD
Additional Cases	TBD	TBD	TBD
Skin Smear Interpretation	If skin smears were performed, please select the results.	TBD	TBD
Date of Skin Smear	Date of Skin Smear	TBD	TBD
Medication Administered	What antibiotic was administered to the patient for Leprosy	TBD	TBD
Previous Treatment	Was the patient previously treated for Hansen's Disease	Yes No Unknown (YNU)	TBD
Previous Treatment Duration	If the patient was previously treated, how many months was the patient treated.	N/A	TBD
Date Treatment or Therapy Started	Date the treatment was initiated	N/A	TBD
Contacts Received Prophylaxis	Have any household contacts of the patient started prophylaxis?	Yes No Unknown (YNU)	TBD
Number of Household Contacts	Total number of known or suspected household contacts.	N/A	TBD
Family/Household Contacts Previously Diagnosed	Have any family members or household contacts been previously diagnosed with HD	Yes No Unknown (YNU)	TBD
Number of Family/Household Contacts Previously Diagnosed	List number of diagnosed previously with Hansen's Disease.	N/A	TBD
Relationship to Known	If answer yes to previous	N/A	TBD

or Suspected Contact	question regarding family member diagnosed, please check relationship.		
Additional Cases	If household contacts of the patient were examined, were any additional cases found	N/A	TBD
Patient Status	Indicate the patient's case status	N/A	TBD
History of Post-exposure Prophylaxis	Does the case patient have a history of being of post-exposure prophylaxis for Hansen's disease or tuberculosis (TB)	Yes No Unknown (YNU)	TBD

Leptospirosis	
The impetus/urgency for CDC to add data elements for this condition	<p>New potential risk groups and risk factors and feedback from states/territories and CDC stakeholders on the clarity and usefulness of the case report form and the information collected has been received. The data elements will allow Bacterial Special Pathogens Branch (BSPB):</p> <ul style="list-style-type: none"> • To better understand the clinical presentation and severity of leptospirosis cases in the U.S., which will in turn help: evaluate and revise, if necessary, the U.S. case definition for leptospirosis, inform improved identification of leptospirosis cases by clinicians, and help quantify the burden and outcome of leptospirosis cases in the U.S. • To identify adverse effects of leptospirosis in pregnant patients and their fetus/neonate • To identify potential hotspots for leptospirosis exposure/infection by linking exposure types with exposure location • To detect emerging risk factors/risk groups for leptospirosis in the U.S. • To clarify the questions in the case report form and improve the quality and usefulness of the data collected to better inform public health practice • To inform CDC recommendations on leptospirosis case identification and management, control and prevention, and inform local outreach and prevention efforts

Data Element Name	Data Element Description	Value Set Code	CDC Priority (New)
Number of Weeks Gestation at Onset of Illness	If subject was pregnant at time of illness onset, specify the number of weeks gestation at onset of illness (1-45 weeks)	N/A	TBD
Pregnancy Adverse Outcome	If subject was pregnant at time of illness, did the subject have any	PHVS_YesNoUnknown_CDC	TBD

	adverse outcome to the pregnancy (e.g. miscarriage, stillbirth, neonatal illness or death) related to the illness?		
Clinical Manifestation Indicator	For each clinical manifestation reported, indicate (YNU) whether the subject developed the specified manifestation as a result of the illness.	PHVS_YesNoUnknown_CDC	TBD
Medication	What antibiotics were prescribed/administered to the patient for treatment of this illness?	PHVS_YesNoUnknown_CDC	TBD
Hospital Procedure	If subject was hospitalized, were any of the following procedures or treatments done?	N/A	TBD
Sick Animal	Were any animals sick at the time of contact?	PHVS_YesNoUnknown_CDC	TBD
Sick Animal Specified	Specify the sick animal/s the patient had contact with at this location	N/A	TBD
Drinking or Bathing Usage	Did the subject use well water or rainwater collected in cisterns, drums, or other containers for drinking or bathing?	PHVS_YesNoUnknown_CDC	TBD
Treated Well Water or Rainwater	If the subject used well water or collected rainwater for drinking or bathing, was the water boiled, chemically treated, or UV treated prior to use?	TBD	TBD
Flooding Location	Specify the location where flooding occurred		TBD
Pre-existing conditions	Does the patient have any of the following pre-existing medical conditions?	TBD	TBD
Work Location State	Indicate the state where the subject's workplace is located	PHVS_State_FIPS_5-2	TBD
Work Location City	Indicate the city where the subject's workplace is located	N/A	TBD
Work Location Zip	Indicate the zip code where the subject's workplace is located	N/A	TBD
Open Wounds	Did the subject have any open wounds or cuts in the 30 days prior to illness onset?	PHVS_YesNoUnknown_CDC	TBD
Type of Rodent	If the subject saw rodents in the 30 days prior to illness onset, what type of rodent(s) were seen?	TBD	TBD
Highest Titer	If the Microscopic Agglutination	N/A	TBD

Serovar(s)	Test (MAT) was performed, specify the serovar(s) with the highest titer.		
Contact with Sewage	Did the subject have contact with sewage in the 30 days prior to illness onset?	PHVS_YesNoUnknown_CDC	TBD
Activity Type	Indicate the types of activity that led to the selected animal, water or mud contact. Multiple activities can be selected for the type of exposure.	TBD	TBD
Exposure Location City	Indicate the county where the selected exposure occurred	N/A	TBD
Exposure Location State	Indicate the state where the selected exposure occurred	PHVS_State_FIPS_5-2	TBD
Exposure Location Country	Indicate the country where the selected exposure occurred	N/A	TBD
Exposure Location	Indicate the specific location where exposure occurred (e.g. home, work, name of park, name of lake)	N/A	TBD

<i>N. meningitidis</i>			
The impetus/urgency for CDC to add data elements for this condition		<ul style="list-style-type: none"> To make surveillance more comprehensive and informative for public health actions Eculizumab use is currently being collected as a data element. Ravulizumab (Ultomiris®) is a modified version of eculizumab with a longer half-life; it is licensed for treatment of PNH. Eculizumab and ravulizumab have FDA boxed warnings for increased risk of serious meningococcal infection (~2000 times greater risk for meningococcal disease compared to healthy individuals). Given the extremely elevated risk for meningococcal disease, it is important to know if meningococcal disease cases were taking this medication. 	
Data Element Name	Data Element Description	Value Set Code	CDC Priority (New)
Ravulizumab	Was the patient taking Ravulizumab (Ultomiris) at the time of disease onset?	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.888	3

2019 Novel Coronavirus (COVID-19)	
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<p>The impetus/urgency for CDC to add data elements for this condition</p>	<ul style="list-style-type: none"> • To make surveillance more comprehensive through consistent case identification and classification, measure the potential burden of illness, characterize the epidemiology of medically attended and moderate to severe COVID-19 in the United States, detect community transmission, and inform public health response to clusters of illness and efficacy of population-based non-pharmaceutical interventions • To provide more information about risk factors (related cases and conditions, high acuity care needs, healthcare facility exposure, travel, and specimen testing) that have been associated with the SARS-CoV-2 virus • To assist in understanding the transmission and epidemiology of the disease in the U.S. jurisdictions • To update guidance on infection control and prevention
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Data Element Name	Data Element Description	Value Set Code	CDC Priority (New)
Trimester at Onset of Illness	If the case-patient was pregnant at time of illness onset, indicate trimester of gestation at time of disease.	PHVS_PregnancyTrimester_CDC	2
Number of Weeks Gestation at Onset of Illness	If the case-patient was pregnant at time of illness onset, specify the number of weeks gestation at onset of illness (1-45 weeks).	N/A	2
Exposure Indicator	Exposure indicator	PHVS_YesNoUnknown_CDC	1
Reason for Testing	Listing of the reason(s) the subject was tested for COVID-19	TBD	3
Secondary Diagnosis	Did the patient have another diagnosis/etiology for their illness?	PHVS_YesNoUnknown_CDC	3
Secondary Diagnosis Description	If patient had another diagnosis/etiology for their illness, specify the diagnosis or etiology	N/A	3
Clinical Finding	Clinical findings associated with the illness being reported	PHVS_ClinicalFinding_COVID-19	1
Clinical Finding Indicator	Indicator for associated clinical findings	PHVS_YesNoUnknown_CDC	1
Did the Subject Ever Receive a Vaccine Against This Disease	Did the subject ever receive a vaccine against this disease?	PHVS_YesNoUnknown_CDC	1

Vaccination Doses Prior to Onset	Number of vaccine doses against this disease prior to illness onset	N/A	1
Date of Last Dose Prior to Illness Onset	Date of last vaccine dose against this disease prior to illness onset	N/A	3
Vaccine History Comments	Comments about the subject's vaccination history	N/A	3
Date Left for Travel	Date left for travel	N/A	1
Date of Return from Travel	Date of return from travel	N/A	1

Burden

The burden to add 108 data elements to NNDSS is applicable to all 50 states, 5 territories, 3 freely associated states, and 2 cities. Although not all territories and freely associated states use electronic, automated transmission for their case notifications, it is expected that they will adopt electronic, automated transmission in the next three years. This burden includes the one-time burden incurred by the respondents to add the data elements to their surveillance system and modify their case notification message. A one-time average burden of 11 hours is incurred for respondents to add 108 data elements to their surveillance system and modify their electronic case notification message to accommodate those 108 additional data elements. This one-time burden of 11 hours is noted in the following table:

One-Time Burden to Add 108 Data Elements to NNDSS

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours): One-time Addition of 108 Data Elements
States	50	1	11
Territories	5	1	11
Freely Associated	3	1	11

States				
Cities	2	1	11	
Total				

The total annualized one-time burden is 240 hours (200 hours for states, 20 hours for territories, 12 hours for freely associated states and 8 hours for cities) as noted in the table below.

Annualized One-Time Burden to Add 108 Data Elements to NNDSS

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours): Annualized One-time Addition of 108 Data Elements	Total Annualized One-Time Burden (in hours)
States	50	1	4	200
Territories	5	1	4	20
Freely Associated States	3	1	4	12
Cities	2	1	4	8
Total				240

39 hours were added to the existing burden hours in Table A.12A and Table A.12B below.

A.12A. Estimates of Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden (in hours)
States	Weekly (Automated)	50	52	20/60	867
States	Weekly (Non-automated)	10	52	2	1,040
States	Weekly (NMI Implementation)	50	52	4	10,400
States	Annual	50	1	75	3,750

States	One-time Addition of Diseases and Data Elements	50	1	4	367
Territories	Weekly (Automated)	5	52	20/60	87
Territories	Weekly, Quarterly (Non-automated)	5	56	20/60	93
Territories	Weekly (NMI Implementation)	5	52	4	1,040
Territories	Annual	5	1	5	25
Territories	One-time Addition of Diseases and Data Elements	5	1	4	37
Freely Associated States	Weekly (Automated)	3	52	20/60	52
Freely Associated States	Weekly, Quarterly (Non-automated)	3	56	20/60	56
Freely Associated States	Annual	3	1	5	15
Freely Associated States	One-time Addition of Diseases and Data Elements	3	1	4	22
Cities	Weekly (Automated)	2	52	20/60	35
Cities	Weekly (Non-automated)	2	52	2	208
Cities	Weekly (NMI Implementation)	2	52	4	416
Cities	Annual	2	1	75	150
Cities	One-time Addition of Diseases and Data Elements	2	1	4	15
Total					18,675

A.12B. Estimates of Annualized Cost Burden

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in	Total Burden Hours	Hourly Wage Rate	Respondent Cost
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				hours)			
States	Weekly (Automated)	50	52	20/60	867	\$46.23	\$40,081
States	Weekly (Non-automated)	10	52	2	1,040	\$37.64	\$39,146
States	Weekly (NMI Implementation)	50	52	4	10,400	\$46.23	\$480,792
States	Annual	50	1	75	3,750	\$37.64	\$141,150
States	One-time Addition of Diseases and Data Elements	50	1	4	367	\$46.23	\$9,246
Territories	Weekly (Automated)	5	52	20/60	87	\$46.23	\$4,022
Territories	Weekly, Quarterly (Non-automated)	5	56	20/60	93	\$37.64	\$3,501
Territories	Weekly (NMI Implementation)	5	52	4	1,040	\$46.23	\$48,079
Territories	Annual	5	1	5	25	\$37.64	\$941
Territories	One-time Addition of Diseases and Data Elements	5	1	4	37	\$46.23	\$925
Freely Associated States	Weekly (Automated)	3	52	20/60	52	\$46.23	\$2,404
Freely Associated States	Weekly, Quarterly (Non-automated)	3	56	20/60	56	\$37.64	\$2,108
Freely Associated States	Annual	3	1	5	15	\$37.64	\$565
Freely Associated States	One-time Addition of Diseases and Data Elements	3	1	4	22	\$46.23	\$555
Cities	Weekly (Automated)	2	52	20/60	35	\$46.23	\$1,618
Cities	Weekly (Non-automated)	2	52	2	208	\$37.64	\$7,829
Cities	Weekly (NMI Implementation)	2	52	4	416	\$46.23	\$19,232
Cities	Annual	2	1	75	150	\$37.64	\$5,646
Cities	One-time Addition of Diseases and Data Elements	2	1	4	15	\$46.23	\$370
Total							\$817,501